

PD-ABM-309

PROJECT AWARD NO. 188.20A, AMENDMENT NO. 1
ACTIVITIES TO ENHANCE THE INTRODUCTION OF THE COPPER T 380A IUD
SUBSTANTIVE REPORT NO. 1

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Submitted by:	Program for Appropriate Technology in Health (PATH, formerly PIACT)
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Appendix A: "Copper T 380A: Guidelines for Informed Use"

I. GOALS AND OBJECTIVES

The overall goal of this project, "Activities to Enhance the Introduction of the Copper T 380A IUD," is to make possible the smooth introduction and transition to widespread use of the Copper T 380A intrauterine device (IUD) in public- and private-sector family planning (FP) service delivery programs in various developing countries.

In order to accomplish this goal, the Program for Appropriate Technology in Health (PATH, formerly PIACT) has formulated the following objectives:

- A. To share information between and among other cooperating agencies (CAs) and organizations involved in introducing the Copper T 380A IUD in FP programs.
- B. To provide decision makers and program managers in developing countries with updated information to assist them in making policy and program decisions.
- C. To adapt for use in country-specific situations a variety of Copper T 380A materials prepared previously in cooperation with the Population Council.
- D. To focus increased attention on the informational and counseling needs of Copper T 380A acceptors and potential acceptors.
- E. To develop materials that can contribute to improved, more effective training for the various levels of service providers, each of which has specific informational requirements, depending upon job responsibilities.

II. BACKGROUND

This project is a continuation of Population Council Award No. 186.36A. The project began on October 15, 1986, and was originally a one-year project. Since the interest of less developed country (LDC) institutions in receiving assistance was slow to build, and since PATH had some matching funds from a private donor, several no-cost extensions were requested by PATH and approved by the Population Council. Thus, funds for project No. 186.36A were not exhausted until June 30, 1988.

The Population Council and PATH anticipated that the first-award funds would not last beyond March 31, 1988. Therefore, a second award, No. 188.20A for \$85,250, was granted to PATH "for a period of six months, beginning on or about April 1, 1988." In July, 1988, the Population Council amended the above-numbered award to \$225,251 and extended its term to December 31, 1989.

PATH's last substantive report under award No. 186.36A covered January 1-June 30, 1988, activities. It would be redundant to repeat a description of April 1-June 30, 1988, activities in this report. Also, to avoid confusion, all activities conducted during the three-month period when the two awards overlapped were paid for with money received under the first award, No. 186.36A.

Therefore, this first substantive report for award 188.20A, while defined in the award letter to cover April 1-December 31, 1988, actually covers July 1-December 31, 1988. In July 1988, Carol Hendrick was consulted about the overlap of the two awards, and she advised PATH that this reporting procedure would be appropriate.

III. GLOBAL ACTIVITIES

A. Information Sharing with the United States Agency for International Development (USAID), USAID Missions, USAID CAs, and Other Organizations Involved in Copper T 380A IUD Activities

A variety of activities has been carried out in order to improve coordination between the institutions involved in Copper T 380A introduction. Particular emphasis has been placed on ensuring that standardized information regarding insertion, contraindications, counseling, etc., is provided by all sources and that every country receiving Copper T 380A IUDs gets the information either prior to or during the IUD's introduction.

1. Field staff of John Snow, Incorporated's Family Planning Logistics Management Project (FPLM) and Center for Development Communication (CDC) have reported instances of countries receiving the Copper T 380A without information regarding its clinical trial history, reasons for it replacing the Lippes Loop and the Copper T 200B, and its similarity to or differences from other IUDs in terms of insertion technique, effectiveness, and shelf life. PATH representatives participated in a meeting with FPLM and USAID staff to discuss possible strategies to make FP personnel more aware of the "features" of this new IUD and to ensure proper training in insertion, patient care, and counseling.

Various strategies were identified, including supplying FPLM staff with copies of some PATH-developed educational brochures to share with in-country FP personnel. FPLM staff will also encourage its counterparts to contact PATH (and vice versa) for materials and/or technical assistance (TA), when appropriate.

2. Another outcome of the FPLM/USAID/PATH meeting was a global cable sent to USAID Missions about the Population Council's project to enhance the introduction of the Copper T 380A IUD. PATH drafted the cable, which announced the availability of PATH TA and materials (see section

III C) for decision makers, clinicians, health workers, and users. Following review by FPLM and USAID, the cable was sent on November 23, 1988, to all USAID Missions. To date, 24 countries have responded to the cable with requests for materials, information about the Copper T 380A, and/or TA. Since the revised materials have not yet been printed (see section III C), an interim informational "mini-packet" has been prepared. Packets of the updated materials will be distributed as soon as they are available.

3. As described ahead (section III C), PATH has revised the documents included in the packet of prototype Copper T 380A materials. During this revision process, PATH has shared drafts of the materials with the Population Council, USAID, and selected CA staff for technical review. This review has not only improved the technical content of the materials but also ensured greater standardization of information with materials being developed by other organizations, such as Program for International Training in Health (INTRAH).

B. Assistance to Introduction Activities

1. The search continues for an ideal pelvic model that can be used by clinicians to practice the correct insertion technique and also by paraprofessionals to explain to new and potential acceptors where the Copper T 380A is placed and why it remains in the uterus. The pelvic model also must be affordable to LDC FP programs. PATH's procurement department has reviewed models from eight American companies and one Thai company. Quality varies substantially, as do prices. At the low end of the scale, a model weighing 1 lb is available for approximately \$10.00 but looks more like a display box than an insertion model. The most expensive model evaluated weighs 45 lbs, costs \$450.00, and is designed for training medical personnel to perform pelvic exams and IUD insertions.

Of the models evaluated, PATH's analyst recommended the Gaumard model Sima 36 for its low cost (\$189.75), low weight, flexibility of material,

and functionality. PATH has purchased this pelvic model and will take it on subsequent trips to Bangladesh and Egypt to discuss possible purchase and use of this model (or a less expensive variation) in both training and clinic situations.

PATH staff has also contacted Gaumard Scientific Company's Vice President and has suggested adjustments to its existing model to make the model more appropriate for use in LDCs. Producing prototypes can get very expensive; PATH is not yet prepared to have a model developed to exact specifications.

2. PATH's last report under Award No. 186.36A mentioned that there was so much demand for a Spanish version of the 1987 prototype flyer for decision makers that PATH was preparing a Spanish version. However, that has not happened. Translation costs proved manageable, but testing the Spanish vocabulary in Latin American countries and agreeing on language that was regionally acceptable turned out to be an overly ambitious project. In addition, there were no funds in PATH's grant for this activity.

3. PATH has printed an extra 3,000 copies of the English version of the prototype flyer for decision makers and will include it in the prototype packets currently being prepared (see III C).

4. In Egypt, a client-oriented booklet on the Copper T 380A has been designed (based on qualitative research findings), tested, revised four times, and is now being printed. This mainly pictorial booklet will be used as part of the training of nurses and outreach workers in face-to-face communication and the effective use of support materials.

5. Representatives of USAID, Finishing Enterprises, Inc. (FEI), The Population Council, and PATH met on November 9, 1988, to reach a consensus on the loading and insertion instructions for the Copper T 380A IUD. A process for loading and insertion was agreed upon, and a PATH staff member wrote the instructions, which have been incorporated

into the updated version of the clinicians manual. These instructions have also been adapted by FEI for the clinician information sheets provided with the IUDs.

6. Reports stating that clinicians are concerned about the discoloration of the copper on some IUDs and sometimes refuse to use them have been received from the field. PATH has responded to inquiries about the safety of IUDs with discolored copper, and this issue has been addressed in the revised clinician's manual. It is hoped that reassurances in the manual (that the oxidation does not affect the usefulness of the copper) will prevent discarding of good IUDs.

C. Revised Packet of Prototype Copper T 380A Materials

During the past six months, PATH has reviewed all the item to be included in the packet of prototype Copper T 380A materials, updated several of these materials, and developed a few new materials in response to needs expressed by collaborating agencies. All revised and new materials have been reviewed thoroughly by experts in the field.

PATH is now preparing a package to be sent to each of the organizations distributing the Copper T 380A. This package includes a brief introductory letter, a description of each of the items, an order form, and samples of those items which are in ample supply or are very new. Interested organizations may order the entire packet or several combinations of materials to suit their informational and/or training needs. Once enough orders are received, PATH will begin printing and distributing the Copper T 380A packet.

A response/comment form will be included with each packet so that PATH and the Population Council will have a better idea of the usefulness of the packet in the field, how it is being used in the field, and whether

the information in each material is consistent with the information disseminated in individual programs.

Following is a description of each item to be included in the revised Copper T 380A packet.

REVISED MATERIALS

Folder: The cardboard folder, with an illustration of a Copper T 380A IUD on its cover, is a handy carrying case for the other materials. The new version is similar to the old version but is a deeper shade of blue.

The Copper T 380A: A Manual for Clinicians: This manual provides important information for clinicians on the advantages of this IUD, clinical procedures, management of complaints and complications, special warnings, and replacement and removal of the Copper T 380A. This "new, improved" version includes detailed loading and insertion instructions, improved illustrations, and data from newer studies than the original version. A uniform loading procedure, developed in consultation with several organizations and licensees, is being recommended.

The Copper T 380A: A Manual for Health Workers: This manual is designed specifically for health workers who interact with clients and has a greater emphasis on counseling than did its 1984 version. The new version has improved text and illustrations, basic information on the benefits, effectiveness, side effects, contraindications, insertion, and management of complications or expulsion of the IUD. This manual is designed to serve as a reference material for health workers whose job it is to motivate, educate, and/or counsel new and prospective IUD clients.

Client Booklet: The client booklet, designed in 1987 and currently used in Bangladesh, illustrates one version of a material developed for low-literate and illiterate clients. It is a useful reference for those

program managers and health educators who wish to adapt or develop appropriate materials for their clients.

NEW MATERIALS

Information Sheets: These four staggered sheets cover a variety of topics about which decision makers need information, including:
1) facts about the Copper T 380A, 2) commonly asked questions and answers about the Copper T 380A, 3) a comparative mortality chart which compares the number of women who die from pregnancy-related causes versus contraceptive complications, and 4) information about adapting the prototype IUD materials for local use.

Wall Chart: This new two-color wall chart is designed to remind clinicians of loading and insertion instructions for the Copper T 380A IUD. The wall chart is intended to be posted in the clinic in an appropriate place, for example, where preparation for IUD insertion is done.

"The Copper T 380A: Guidelines for Informed Use": This indexed, staggered-paged brochure provides decision makers and program managers with guidelines on appropriate and informed use of the Copper T 380A IUD.

Flyer: This material, developed in 1987, gives decision makers and program managers a concise overview of the Copper T 380A's advantages, disadvantages, and contraindications for use. It also describes the elements of a successful Copper T 380A program.

Reprints: PATH will include in each packet a few reprints of journal articles as well as the 1988 issue of *Population Reports*, devoted to IUDs.

D. Second Mailing for Decision Makers

A small, indexed, staggered-paged brochure, "Copper T 380A: Guidelines for Informed Use," was printed in December 1988. As was the 1987 PATH flyer, this brochure will be sent to third world Ministry of Health (MOH) officials from the offices of planning, population, drug regulation, and maternal and child health; heads of FP associations and other private-sector FP programs; heads of hospitals and departments of OB/GYN; and overseas representatives of donor organizations working on health and FP programs.

As the title implies, this brochure provides decision makers and program managers with guidelines for appropriate and informed use of the Copper T 380A IUD. Much of the information it contains was adapted from a report by the U.S. Centers for Disease Control, which sponsored a one-day meeting on this topic in September 1986.

This new brochure will also be included in the revised Copper T 380A packet of prototype materials.

IV. COUNTRY ACTIVITIES

A. Bangladesh

PATH's previous report outlined plans to distribute Copper T 380A clinician's and motivator's manuals by post and to training centers. The latter was to be achieved through orientations of health worker trainers in collaboration with the National Institute for Population Research and Training (NIPORT).

The postal distribution of the Copper T 380A manuals was quite successful. An initial, exploratory mailing to field staff in 128 upazillas and 64 districts was completed in late October 1988. By November 28, 1988, the nongovernmental organization (NGO) which mailed the manuals received acknowledgement of receipt from a majority of the

sites. As a result, the rest of the materials were sent to the remaining upazillas. The entire task was completed by the first week in December 1988. Since then, the distributor has received additional requests for materials from NGOs.

NIPORT is very supportive of the proposed project. However, Concerned Women for Family Planning (CWFP) is still awaiting government permission to receive PATH funds. The governmental approval process was recently changed, which may be the reason for the delay.

Since only one year's worth of manuals will go to the Family Welfare Visitor Training Institutes (FWVTIs) and the Regional Training Centers (RTCs), the storage of the remaining manuals was an issue. However, NIPORT has recently relocated, and sufficient storage space may be available in its new building.

As originally planned, the Copper T 380A client's booklets are being distributed to five selected upazillas by another NGO, the Bangladesh Rural Advancement Committee (BRAC), and through government distribution channels on a trial basis.

B. Colombia

PATH has provided TA to the Asociación Sociedad Médico Farmacéutica (SOMEFA) to develop Copper T 380A educational materials for physicians and clients. To date, the following materials have been developed: three informational brochures for physicians and one for clients, a SOMEFA product request form, and a patient appointment card. A physician's reference manual covering IUD insertion and removal techniques and a manual for field workers were also prepared for use in Colombia. These manuals were adapted from the prototype manuals developed by the Population Council and PATH.

The usefulness and acceptability of the brochures were measured using a questionnaire which was distributed to 10 percent of the physicians who

were sent the brochures. Although only 17 percent of the sampled physicians responded to the questionnaire, over 90 percent of responding physicians received the brochures and indicated a desire for additional copies. Over two-thirds of those responding found the materials useful and liked the materials' content, format, and overall appearance. A second evaluation was designed to determine the indirect effect of the brochures on the number of requests for products received from physicians who were sent the brochures as compared to the number of requests received from a control group. Between February and August 1988, 7 percent of the physicians who were sent the brochures requested IUDs and other products from SOMEFA. Fifty-two percent of all IUDs sold by SOMEFA during the evaluation period were bought by physicians who had been sent the brochures. SOMEFA also reported that an additional 575 copies of the client's brochure and 100 copies of the physician's counseling brochure were sent upon doctors' requests.

C. Brazil

PATH is collaborating with the Population Council and the Center for Research and Control of Maternal and Child Diseases (CEMICAMP) of the University of Campinas in São Paulo, Brazil, to assist in the design, implementation, and evaluation of materials and training curricula to facilitate the introduction of the Copper T 380A into São Paulo state health and FP services. Because public-sector FP programs are very new in Brazil and the IUD is not a well-known contraceptive,¹ the emphasis of these project activities is on improving quality of care by focusing on provider competence and counseling. It is hoped that the São Paulo state program will become a model for other states and/or the federal Ministry of Health (MOH).

In July 1988, two PATH staff members visited Campinas and provided TA to CEMICAMP staff in the following areas: the design of a training

¹ At present, only 1 percent of women in São Paulo State who use a contraceptive method (approximately 70 percent of women of fertile age) use an IUD.

curriculum for physicians; the design of a training curriculum for counselors; the development or adaptation and testing of materials for physicians, counselors, and clients; and the development of a strategy to evaluate training. The training curriculum for physicians was pilot-tested in October 1988 and is now completed. It includes 14 half-day sessions dedicated to clinical practice as well as counseling and interpersonal communication. The training curriculum for counselors has also been pilot-tested and is scheduled to be completed in January 1989. Since many of the people who will serve as counselors have no prior training in FP or counseling, the curriculum includes training in the various contraceptive methods used in Brazil plus exposure to and practice in many of the skills needed to be an effective FP counselor.

A series of additional materials to support Copper T 380A introduction was also developed. A subgrant from PATH (from its Population Council grant) will support the cost of printing these materials. Many of these have been adapted from prototype materials previously prepared by PATH and the Population Council. All these materials have been pretested with the target audience and are now being printed. They will be ready in January 1989.

The materials include:

- *The Copper T 380A: A Manual for Physicians*, which was adapted from the PATH/Population Council 1985 version;
- *Questions and Answers About the Copper T 380A for Family Planning Counselors*, which was adapted from the PATH/Population Council 1984 version of the manual, *Copper T 380A: A Handbook for Field Workers*;
- "The Copper T 380A," a brochure for physicians which was adapted from the 1987 PATH brochure;

- "Guidelines for Informed Decision Making and Use of the Copper T 380A IUD," a brochure for physicians which was adapted from the 1988 PATH brochure, "The Copper T 380A: Guidelines for Informed Use";
- *Manual for Family Planning Counselors*, which contains general counseling guidelines;
- "Pregnancy and Contraception: We Inform, You Decide," a 14-page flip chart on all contraceptive methods available in Brazil; and
- "The Copper T 380A," a comic book-style booklet for users.

D. Tunisia

During a meeting attended by representatives of RONCO and PATH in early April 1988, RONCO informed PATH that the Tunisian Office National de la Famille et de la Population (ONFP) might be interested in receiving TA in Copper T 380A introduction-related activities.

After corresponding with ONFP, PATH staff met with Professor Hedi Mhenni, president and director of ONFP, at the National Academy of Sciences conference on population in October 1988. Professor Mhenni expressed his interest in having PATH staff members schedule a TA visit to assist ONFP in various aspects of its national program as it relates to Copper T 380A IUD introduction and/or use. Subsequent correspondence between PATH and ONFP staff ensued in November and December 1988, and on December 5, PATH received official confirmation from ONFP for a two-person TA visit to be carried out January 15-23, 1989.

V. FUTURE ACTIVITIES

A. Bangladesh

During a field visit to Bangladesh scheduled for January 1989, a PATH staff member will determine the status of the field-use study for the

Copper T 380A client's booklets. This study is being implemented by BRAC. PATH will also investigate alternatives to the NIPORT training by CWFP if the government continues to delay approval of the project. A contract with an implementing agency would be initiated as soon as possible. PATH will, if possible, develop a small follow-up evaluation of the use of the manuals at FWVTIs and RTCs.

PATH will also take advantage of this opportunity to inform all FP organizations about the Copper T 380A materials and urge groups to use them in their programs so that, eventually, uniform information on this product will be transmitted throughout Bangladesh.

B. Colombia

A proposal has been prepared with the MOH to develop Copper T 380A materials. The materials to be developed include one informational brochure for users and one for potential users. The proposed project is planned for January-December 1989. An information, education, and communication (IEC) workshop on materials development is scheduled to take place February 6-10, 1989. This workshop will begin the process of technology transfer and thus provide participants with the methodological training they need to design materials for any audience on a variety of topics.

C. Brazil

In late February 1989, a training of trainers (TOT) workshop for six physicians will be held at the University of Campinas. Each trainer represents a major medical school in Sao Paulo state. These six physicians will in turn be responsible for training an additional 50 to 80 physicians each, over a period of six months. A TOT for approximately 12 counselors, two from each of these medical schools, will be held later. These trainers will then train an additional 480 counselors.

It is hoped that these training centers will become training centers for the introduction of other FP methods as well as model training centers for Brazil. The effectiveness of the training will be evaluated through pretraining and posttraining tests and additional posttraining follow-up, including intercept interviews with clients and observation. CEMICAMP has requested PATH assistance for the first training session and in refining the evaluation design and instruments.

D. Tunisia

In January 1989, PATH will proceed with the two-person TA visit to Tunisia with the objective of assisting ONFP staff in designing an overall IEC strategy for Copper T 380A IUD introduction activities. Based on the results of this visit, PATH will provide assistance as requested. Areas in which PATH staff may be of further assistance include: the preparation of a training curriculum on counseling/face-to-face communication, the development of Copper T 380A materials for low-literates, the adaptation of a counseling guide for health workers, and/or the development of a reference manual for clinicians.

E. Egypt

As a result of the cable that USAID/Washington sent to its Missions, PATH has been asked to provide TA to Egyptian organizations that wish to adapt some of the materials in the prototype package. A PATH staff person is tentatively scheduled to visit Egypt in late-March-April 1989 to assist counterparts in adapting these materials to suit their FP program needs.

F. Worldwide Efforts

Future worldwide activities also include the following:

1. After receiving orders from CAs, PATH will print and distribute the Copper T 380A prototype packets (see section III C for more detail).

2. The wall chart with instructions for loading and inserting the Copper T 380A IUD will be finalized and printed.

3. As was recommended at the March 1988 IUD Interagency Meeting, PATH will prepare a 2-3 page prototype handout for trainers of service providers who will be inserting IUDs. This handout will be designed to serve as a reminder of points that the trainer should highlight and emphasize during the training.

4. The International Planned Parenthood Federation (IPPF)/London is preparing a training video on all aspects of Copper T 380A IUDs: client selection, client counseling, IUD insertion, follow-up, and IUD removal. PATH has shared with IPPF draft versions of the wall chart and the new clinician's and field worker's manuals to ensure that the instructions for loading, inserting, and client counseling will be consistent with instructions and language already approved by The Population Council, USAID, and FEI. At IPPF's request, PATH will review the video script.

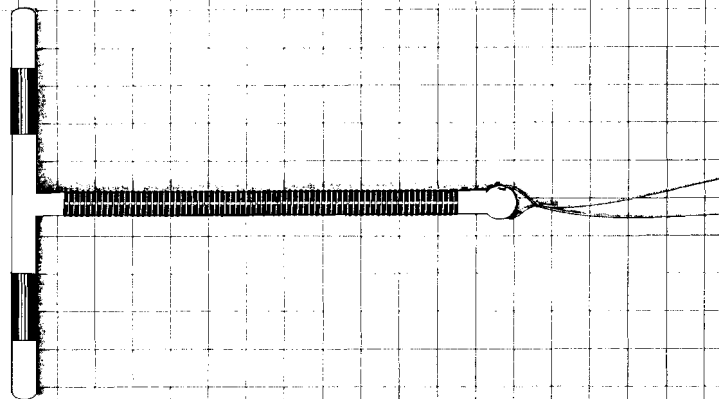
PATH has also offered to work with IPPF to pretest the video before it is finalized. A well-understood and acceptable video could be a most useful training tool in all third world countries in which this model IUD is being used. The video could be adapted easily by using a voice-over in the local language. Currently there is no suitable Copper T 380A training video or film. Since one is now being developed, PATH would like to help ensure that it is as well-executed and effective as possible.

5. PATH will organize representatives of several interested CAs into a committee to develop a uniform set of Copper T 380A IUD standards and practices. (This is another recommendation of the IUD Interagency Meeting that needs to be implemented.) Volunteers from RONCO, The Johns Hopkins Program for International Education in Gynecology and Obstetrics, and Family Health International have been identified, but thus far conflicting travel schedules have precluded PATH's going beyond the "talking stage."

6. A two-day interagency meeting, similar to the March 1988 meeting, will be organized in May or June 1989. This meeting will focus on how to improve training and develop expertise at the clinic level. The meeting will also provide an opportunity for participants to examine all existing materials and videos as well as to function as a "trial" for regional meetings to discuss training.

7. A Population Council/PATH meeting was held on December 19, 1988, to develop strategies for future introductory activities. A "wish list" of possible activities, overall project goals, and subjects for a concept paper were developed. Activities outlined during this meeting will help define the direction of future activities.

COPPER T 380A



APPENDIX A

GUIDELINES FOR INFORMED USE

SIDE EFFECTS

FOLLOW-UP

INSERTION

COUNSELING

SCREENING

GENERAL INFORMATION

INTRODUCTION

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